



10/629,490

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: KNUDSON ET AL. Examiner: S. GILBERT
Serial No.: 10/629,490 Group Art Unit: 3736
Filed: JULY 29, 2003 Docket No.: 13033.1USC8
Title: AIRWAY STIFFENING IMPLANT (as amended)

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 on November 17, 2005.

By: Linda M. Beckman
Name: Linda M. Beckman

DECLARATION OF PAUL J. BUSCEMI, PH.D.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Paul J. Buscemi declares as follows:

1. In 2005, I became Vice President, Research & Development of Restore Medical, Inc., assignee of the above-referenced patent application ("Patent Application").
2. I submit this declaration in response to a July 1, 2005 Patent Office action in the Patent Application. I have reviewed the following in advance of this Declaration:
 - a. The Patent Application
 - b. The July 1, 2005 Patent Office action in the Patent Application
 - c. U.S. Pat. No. 5,979,456 ("Magovern")
 - d. U.S. Pat. No. 6,106,541 ("Hurbis")
 - e. U.S. Pat. No. 5,176,618 ("Freedman")
 - f. German Patent DE 44 12 190 A1 ("Schreiber") (English translation)
3. My relevant education is as follows:
 - a. I received a B.S. degree in Physics from the University of Florida – Gainesville in 1968.

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- b. Following a period of military service, I received a Ph.D. from the University of Florida – Gainesville in 1978. The Ph.D. is in biomaterials. My education and doctorate research was heavily focused on implant materials and tissue response (including fibrotic response) on a wide variety of materials including polymers (including polyester, polytetrafluoroethylene (PTFE) and expanded polytetrafluoroethylene (ePTFE)), metals (including shape memory metals such as nitinol) and ceramics.
- c. Following my Ph.D., I did post-doctorate work at the University of Florida – Gainesville until 1980.

4. My relevant work experience is as follows:

- a. From 1980 to 1983, I did surface chemistry work at Ashland Chemical, Ohio (this work did not include evaluating tissue response to implants).
- b. From 1983 to 1988, I worked for British Oxygen Corp. (BOG), New Jersey developing and evaluating polymer surface coatings and interactions with blood as part of developing bio-compatible coatings for catheters.
- c. From 1988 to 1995, I worked for SciMed (a division of Boston Scientific), Maple Grove, Minnesota developing and evaluating cardiovascular stents. This work included evaluating tissue response of stent materials including nitinol.
- d. From 1995 to 2005, I worked for Advanced Biosurface, Minnetonka, Minnesota. This work included evaluating tissue response to orthopedic implants.

5. Based on my review of the documents described in paragraph 2, above, my education and experience, I make the following observations and conclusions regarding U.S. Pat. No. 5,979,456 (“Magovern”):

- a. Magovern describes various concepts for treating obstructive sleep apnea. My remarks will focus on the concepts disclosed with reference to Figures 8-10 of Magovern. The implants of Magovern are described as one or more suture-like threads of shape-memory material inserted into the musculature as described in Magovern on column 7, lines 25-59. Various shape-memory materials are described in column 5, lines 48-56 and include nitinol (nickel titanium alloy), CuZnAl and CuAlNi alloys.

- b. The implants of Magovern are selected to have no impact on the pharyngeal wall or other anatomical structures except when activated by application of energy from a source. The application of energy can be heating (e.g., by electrical current) or cooling.
- c. The material of Magovern would not have a significant fibrotic response when implanted in the musculature of the pharyngeal wall. The description of a "suture-like thread" would lead one of ordinary skill in art to recognize Magovern is using extremely thin shape-memory metal threads of about 0.5 millimeters in diameter. Such metals are well known as having a low fibrotic response. That is one of the reasons such shape-memory metals like nitinol are used in cardiovascular stents where fibrosis is an event to be avoided. Any fibrosis that might result from Magovern would be extremely minuscule. For example, for a 0.5 millimeter diameter suture-like thread of nitinol or the other shape-memory metals described in Magovern, the thickness of a surrounding fibrosis layer might be in the order of 20 to 50 microns which is equivalent to a thickness of a few layers of cells of the tissue.
- d. The minuscule fibrotic response, if any, of the material of Magovern would not alter the dynamic response of the tissue to air flow. One of ordinary skill in the art reading the Patent Application would recognize that the Patent Application is describing, in certain embodiments, implant of materials that are selected to induce fibrosis in a material amount with material meaning imparting to the tissue a resistance to deformation. Magovern and the other cited references to no show or suggest such materials.

6. Based on my review of the documents described in paragraph 2, above, my education and experience, I make the following observations and conclusions regarding U.S. Pat. No. 6,106,541 ("Hurbis"):

- a. Hurbis teaches an implantable nasal dilator which is placed over the cartilage or bone structure of the nose and beneath the skin layer. Hurbis would suggest to one of ordinary skill in the art a selection of material for avoiding any fibrotic response. Any substantial fibrotic response would result in a bulking of the tissue

layer directly beneath the skin which would make for visibly perceptible bulk in the nose in the region of the implant with adverse cosmetic effects.

- b. As a result of the need to avoid fibrotic response, the nasal dilator 10 of Hurbis has an internal skeletal structure 24 (such as stainless steel or nylon) which is surrounded by an external encasing sheath 26. (Hurbis, column 3, lines 28-50.)
- c. The external encasing sheath 26 of Hurbis is preferably expanded polytetrafluoroethylene. This material is commonly referred to as ePTFE. ePTFE may or may not have a fibrotic response depending on how it is formed. ePTFE can be formed as a smooth material or can be formed as a frayed material with substantially enhanced surface area. As a smooth material, ePTFE has extremely low fibrotic response which would not be material in amount and would not alter the dynamics of the tissue response to air flow. While Hurbis does not show the specific method of forming the ePTFE, I believe one of ordinary skill in the art would read Hurbis in its entirety to have a smooth structure since such a structure is shown in the drawings (Figure 4) and Hurbis would want to avoid fibrotic response to avoid a bump in the nose having adverse cosmetic response.

7. Based on my review of the documents described in paragraph 2, above, my education and experience, I make the following observations and conclusions regarding U.S. Pat. No. 5,176,618 (“Freedman”):

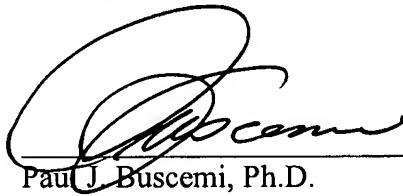
- a. Freedman uses cooperating magnets. At least one of the magnets is imbedded within tissue. The other magnet may be external (such as in a collar 9 in Fig. 1) or in an opposing tissue such as imbedded within the tongue 58 or epiglottis 32 as shown in Fig. 1. Fig. 5 shows the opposing magnets in other anatomical structures.
- b. In all of the embodiments of Freedman, a force provided by a device external to the implant (namely a second implant placed in separate tissue) is required for efficacy.
- c. The magnets of Freedman are not flexible. They are rigid. This can be determined by reviewing column 6, lines 40-44 of Freedman where Freedman describes the particular magnet material which will be recognized by those of skill in the art as being rigid materials.

- d. The device of Freedman does not have a material fibrotic response. Instead, Freedman coats this magnetic material with a smooth polymer coating (such as urethane or silicone as used in heart pacemaker implants). (See Freedman, column 7, lines 4-9.) These materials will be recognized as one of skill in art of having an extremely low fibrotic response which would be insufficient to impart a stiffness to airflow past the tissue.
- 8. Based on my review of the documents described in paragraph 2, above, my education and experience, I make the following observations and conclusions regarding German Patent DE 44 12 190 A1 ("Schreiber"):
 - a. The Schreiber disclosure will be recognized by one of ordinary skill in the art as being a flowable liquid which is susceptible of being injected through a hypodermic needle. Schreiber is attempting to delay the resorption rate of collagen by impregnating the collagen with cross-linked fillers before injection of the collagen into tissue.
 - b. The text of Schreiber (including the claims) indicates Schreiber is referring to injection of flowable, injectable collagen and not a solid of preformed dimensions. Schreiber refers to repeated injections to achieve a desired stiffness while avoiding the adverse effect of a change in the voice. For example, Schreiber states that collagen "is injected successfully and beginning with small doses while observing the change of the voice." These terms would be recognized by one of ordinary skill in the art as referring to a flowable, injectable material and not a material, which is a solid of preformed dimensions.
- 9. I am not an inventor of the patent application. However I reviewed the Patent Application and note that it describes a number of different embodiments. Some of these are described as fibrosis-inducing materials, which can be accomplished by either having surface area which is enhanced (for example, by sintering as described on page 20, line 21). One of ordinary skill in the art would recognize that sintering will enhance fibrotic response as described in the Patent Application. The Patent Application also describes tissue in-growth surfaces (p. 9, line 8) and certain materials (polyester – p. 7, line 23) which encourages tissue in-growth and which also induces substantial fibrotic response as known to those with biomaterial experience and training. Such materials induce a

substantial fibrotic response, which will stiffen surrounding tissue unlike the minimal, if any, fibrotic response of the references cited in the Office Action. In addition to stiffening through fibrotic response, the Patent Application also describes stiffening by reason of the mechanical strength of the material which can be flexible to avoid impeding the function of the tissue (e.g., p. 8, lines 25 – 30). The stiffness of the material and stiffness due to fibrotic response can alter an otherwise flaccid tissue, which may have become flaccid due to either lack of muscle tone or other reasons.

10. I make this statement based upon my own information and knowledge and the facts recited in this Declaration are true and correct to the best of my knowledge. The foregoing statements are made of my own knowledge and are true. I hereby acknowledge I am warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

2 Nov 05
Date



Paul J. Buscemi, Ph.D.